

## REMARKS

The Office Action mailed December 31, 2003 has been received and the Examiner's comments carefully reviewed. Claims 22-46 and 48-58 are currently pending. Applicants respectfully submit that the pending claims are in condition for allowance.

### Rejections Under 35 U.S.C. §103

The Examiner rejected previously allowed claims 22-46 and 48-58 under 35 USC Section 103 over U.S. Patent No. 6,470,883 to Beaudry ("Beaudry") in view of Applicants' own disclosure. This rejection is respectfully traversed. Neither Beaudry nor Applicants' disclosure, alone or in combination, teach or suggest supporting the vestibular walls overlying the nasal passages for reducing exercise induced pulmonary hemorrhage ("EIPH") in horses as recited in the rejected claims.

Initially, Applicants note that aside from a brief reference in Beaudry to use of the mechanism on "humans and/or animals," Beaudry lacks any enabling disclosure of use of the mechanism on an animal. Indeed, not only does Beaudry fail to mention anything more about the use of the disclosed mechanism on an animal, it also fails to make any disclosure regarding use of the mechanism on a horse, as recited in the instant claims. Moreover, Beaudry fails to show a single drawing or description of how such a mechanism would be used on a horse or any other animal. Thus, Applicants submit that not only does this reference fail to disclose use of this mechanism on a horse, it is also non-enabling for use of the disclosed mechanism on any animal.

The Examiner further cited to page 3 of Applicants' disclosure for the proposition that "it was at least hypothesized that EIPH was caused by asphyxia due to a closed upper airway." Applicants' believe the Examiner was referring to the statement at page 3, lines 9 to 16, where it is stated:

Some experts have theorized that exercise induced pulmonary hemorrhage (EIPH) in performance horses is caused by asphyxia due to abnormal resistance of a

closed or partially closed upper airway. The upper airway being defined as the region of the respiratory tract lying between the nostrils and the windpipe at the level of the first rib. Hence the nasal passages are part of this region. Dr. Robert Cook, "EIPH or AIPE A Tufts University Researcher suggests that bleeding is not caused by EIPH, but by asphyxia. *The Equine Athlete*, p. 22-23 (March/April 1997).

Applicants noted after reviewing the Examiner's rejection that although specifically identifying the cited reference in the specification, the cited reference was inadvertently not submitted in an Information Disclosure Statement. A Supplemental Information Disclosure Statement is filed herewith including the cited reference ("Cook"), which is a break out box of a larger article entitled "EIPH: What we know about bleeding, Brent Kelley, DVM, *The Equine Athlete*, p.21-27 (March/April 1997) ("Kelley").

Review of both Cook and Kelley clearly show that the use of a nasal strip as recited in the present claims was neither taught nor suggested in these references. At page 24 Kelley provides a list of causes of EIPH and at page 26, Kelly discusses "Treatment" and "Managing the bleeder". Neither of these discussions teaches, suggests or otherwise indicates that either the nasal passages or support of the nasal passages of a horse reduces EIPH as claimed in the present claims.

Cook states:

The primary problem [of EIPH] is not in the lungs but in the upper respiratory tract.

In my opinion, pulmonary edema will occur in any horse that has to breathe in against the *abnormal* resistance of a closed or partially closed upper airway. I define the upper airway as being that part of the respiratory tract lying between the nostrils and the windpipe at the level of the first rib. Fortunately, in

most horses the degree of asphyxia is partial rather than complete....” Cook at 22. (Emphasis added).

Cook’s theory of asphyxia is focused on the throat, including position of the head and neck, and defects or deformities of the larynx and windpipe regions of the upper respiratory tract. Cook then specifically focuses on a particular *abnormality* of the larynx, recurrent laryngeal neuropathy, not the nasal passages:

Eighty percent or more of racehorses in training show evidence of EIPH (AIPE) on endoscopic evidence alone. Upper-airway obstruction in racehorses is quite common enough to explain this high prevalence. First, at racing speeds, any position of the head and neck other than maximum extension constitutes an airflow obstruction at the throat. Secondly, there are many defects of conformation that represent potential sources of upper airway obstruction. Examples include narrow jaws (and therefore narrow throats and larynges) and deformities of the windpipe. Finally, obstruction of the airway is a feature of almost every known disease of the upper airway.

One upper-airway disease that occurs, to varying degrees, in over 95% of racehorses is recurrent laryngeal neuropathy (RLN)....

Cook at pp. 22-23.

Moreover, although Cook theorizes a *cause* for EIPH in the upper respiratory tract, it neither teaches nor suggests the nasal passages as a cause of EIPH nor that support of the nasal passages can *reduce* EIPH in horses. The Examiner's basis for this rejection can only be improper hindsight reconstruction. So, while Applicants' specification discloses a theory of an expert, the expert does not teach or suggest that support of the nasal passages could have the profound effect on reducing EIPH that has been recognized and claimed by the present inventors. Indeed, only after the present inventors brought forth their discovery were numerous studies conducted and papers and textbook sections written confirming this discovery. Thus, in contrast to the Examiner's

position that it would have been obvious to use the Beaudry mechanism on a horse afflicted with EIPH, ongoing research in the veterinary world has only later confirmed the significance of the discovery recited in the present claims. Accordingly, the Examiner's rejection is respectfully traversed.

### SUMMARY

It is respectfully submitted that each of the presently pending claims (claims 22-46 and 48-58) is in condition for allowance and notification to that effect is requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

Although certain arguments regarding patentability are set forth herein, there may be other arguments and reasons why the claimed invention is patentably distinct. Applicants reserve the right to raise these arguments in the future.

Respectfully submitted,



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*Do NOT make final*